

REMARKS

The Office Action mailed March 20, 2007, has been received and reviewed. By the present Response, Claims 2 and 27 are canceled, Claims 1, 3-13, 21, 21-26, and 28-30 are amended, and new Claims 35-39 are added. Currently pending in the application, then, are Claims 1, 3-26, and 28-39, of which Claims 1, 14, 21, 24, 25, 31, and 33 are independent. No new matter has been introduced by this Response. The Applicant respectfully traverses the rejections and requests reconsideration.

Claim Rejections Under 35 USC § 112

Claims 1-13 are rejected under 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 has been amended to expressly claim the combination of the separator and the surgical device. Accordingly, this ground for rejection is overcome.

Claim Rejections Under 35 USC §§ 102 and 103

Claims 1-4, 10, 14-16, 22, 27, 31, and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Levesque et al. (US6610075). Claims 1-4, 14-16, 27, 31, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Carriazo (US6447526). Claims 5-8, 11, 17-20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levesque et al. Claims 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levesque et al. Claims 5-8 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carriazo. And Claims 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carriazo. Claims 2 and 27 are canceled. The rejections of the remaining claims are addressed by claim set for convenience and ease of examination.

Claims sets 1-13 and 14-25 will be addressed first. Claims 1 and 14 recite a separator having a separating edge that is made at least in part of a *polymeric* material.

The polymeric separating edge is not sharp enough to cut into the underlying Bowman's layer—it is "blunt"—so it separates the corneal epithelium from the Bowman's layer while *leaving the Bowman's layer intact*. As discussed in the specification (see para. [0004] to [0006]), all known prior microkeratomes include a sharp-edged knife or blade made of metal, diamond, or a similar hard material. And all known prior microkeratomes, except for that disclosed by Pallikaris et al. (US7004953), which the Applicant has an ownership interest in, include such a knife or blade for cutting all the way through the epithelium and the Bowman's layer, and into the stroma. And while the Pallikaris et al. reference discloses a microkeratome for separating the epithelium from the cornea, even it uses a sharp-edged metal knife for doing so. Thus, until the present invention, all of the research and development in this area was toward finding ways to make blades of harder material that can hold a sharper edge. Conventional polymeric materials are not capable of holding a sharp enough of an edge to perform the precise corneal cutting required in eye surgery. So the prior art, which is voluminous, teaches away from the use of a separator having a *polymeric* separating edge for separating the epithelium from the cornea and leaving the Bowman's layer intact, as is claimed. But this has proven to be a real advance in the field of corrective eye surgery because, among other reasons, the polymeric separators can be made inexpensively enough that they can be used only once and then disposed of. This disposability feature avoids the problems associated with sterilization and contamination from re-use. In addition, by using the blunt separating edge to scrap back only (or almost only) the epithelial layer and expose an intact Bowman's layer, an optical correction can be made to the Bowman's layer and stroma without cutting into and permanently damaging nerves in the Bowman's layer and stroma. Because the epithelial layer is regenerative an only this thin layer is removed, the eye heals much more quickly and completely.

Claims 1 and 14 are rejected based on Levesque et al. and Carriazo. Both of these references disclose improvements to keratomes, but they use conventional sharp-edged blades (such as those described above) that cut all the way through the epithelium and the

Bowman's layer, and into the stroma. In particular, Levesque et al. expressly discloses a keratome with a sharp-edged "metal cutting blade" (see col. 4, lines 8-10). Carriazo does not disclose any particular material, but it refers to the "knife-edged blade" for "cutting" throughout the disclosure, so it is clear that this is a conventional blade made of a conventional metal or similarly hard material. And both Levesque et al. and Carriazo disclose cutting into the cornea with any mention of separating the epithelium from the Bowman's layer and leaving the Bowman's layer intact. The Examiner has pointed to Fig. 4 of Levesque et al. and Figs. 1 and 2 of Carriazo as showing the blades not cutting into the Bowman's layer. But these figures do not show the epithelial, Bowman's, or stromal layers—they are not that detailed and only generally show cutting into the cornea. In addition, the Applicant's attorney searched the Levesque et al. and Carriazo references, both manually and using the "find" feature in WORD, and found no usage in either document of the words "stroma," "Bowman," or "epithelium." So as best as can be determined, these figures merely show the blades cutting into the cornea generally, without any reference to the corneal layer cut into.

For these reasons, the cited references do not disclose, teach, or suggest the claimed blunt polymeric separating edge for separating the epithelium from the Bowman's layer while leaving the Bowman's layer intact. Accordingly, Claims 1 and 14 are believed to be in condition for allowance. Claims 3-13 and 15-25 depend from Claims 1 and 14, so these claims are also believed to be in condition for allowance.

In addition, Claims 3-8 and 15-20 recite further elements of specific polymeric materials that are well suited for use in the separating edge. These specific elements are not disclosed, taught, or suggested by the cited references, and as such they are believed to be in condition for allowance.

Claims 9 and 21 recite the separating edge comprising a polymeric material and an inorganic filler material. Claim 21 is indicated to be allowable and is rewritten in

independent form. Claim 9 includes the same elements as original Claim 21, and as such is believed to be allowable too.

Claims 10 and 11 and Claim 22 and 23 recite the polymeric separating edge comprising a transparent material. These claims are rejected based solely on Levesque et al. But this reference discloses a sharp metal cutting blade that is not transparent (even if transparent metals exist, they are not disclosed in the reference). The transparent part that the Examiner referred to at col. 10, lines 30-32, is an insert into the toe 81 of the foot 80 of the cutter head.” The foot 80 appears to be for applanating (flattening) the cornea before making the corneal cut, as is conventional in the art. Conventional blades useful for the intended function in the art are sharp metal blades, and known metals (in the solid state and at temperatures and pressures that the blades would be used at for their intended function) are not transparent. Thus, the cited reference does not disclose, teach, or suggest a transparent polymeric separating edge, and for this additional reason these claims are believed to be in condition for allowance.

Claims 12 and 24 recite the separating edge comprising a polymeric material that is tinted (in addition to being transparent). Claim 24 is indicated to be allowable and is rewritten in independent form. Claim 12 includes the same elements as original Claim 24, and as such is believed to be allowable too.

Claims 13 and 25 recite the separating edge comprising a polymeric material having a softening-point maximum temperature. Claim 25 is indicated to be allowable and is rewritten in independent form. Claim 13 includes the same elements as original Claim 25, and as such is believed to be allowable too.

Claims 26-30 are rejected based on Levesque et al. and Carriazo. Claim 27 is canceled. Claims 26 and 28 are amended to be dependent from Claim 14, which is believed to be in condition for allowance, as discussed above, so these claims are also believed to be in condition for allowance.

In addition, Claims 26 and 28-30 recite flat and round separating edge profiles, and dimensions to provide bluntness for separating the epithelium from the cornea without cutting into the Bowman's layer. The elements of these claims are disclosed in the application at para. [0036] and the drawings at Figures 3 and 4. Levesque et al. and Carriazo disclose only sharply pointed blades (e.g., Figs. 14-16 of Levesque et al.), as are conventional in the art for cutting into the epithelium, Bowman's layer, and stroma. Thus, the elements recited in Claims 26 and 28-30 are not disclosed, taught, or suggested by the cited references. For this additional reason, these claims are believed to be in condition for allowance.

Furthermore, new Claims 35-37 recite various innovative configurations of the body of the separator that are not disclosed, taught, or suggested by the known prior art. The elements of these claims are disclosed in the application at para. [0038] and [0039] and in the drawings at Figures 6A-C.

Turning now to Claims 31 and 32, they are both rejected based on Levesque et al. and Carriazo. Claim 31 recites the use of a *polymeric* separating edge to separate the epithelium from the cornea *while leaving the Bowman's layer intact*, which is not known in the art, as discussed in detail above. The Examiner has relied on the same basis for rejecting this claim as was used for Claims 1 and 14. For the same reasons as set forth above with respect to those claims, Claim 31 is believed to be in condition for allowance. And Claim 32 is dependent from Claim 31, so it too is believed to be in condition for allowance.

In addition, new Claim 38 recites the step of not constraining the epithelium during the separation. As described in the specification as para. [0053] and [0054], this results in less stress and strain on the epithelium and thus less cell death. And new Claim 39 recites the step of disposing of the separator (with the *polymeric* separating edge) after a single

use. Neither of these recited elements are disclosed, taught, or suggested by the cited references.

Allowable Claims

Claims 21, 24, 25, 33, and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. As indicated above, Claims 21, 24, and 24 have been rewritten in independent form including all of the limitations of base Claim 14 and any intervening claims. Original Claim 33 is an independent claim, and as such it is believed to be in condition for allowance without amendment. Claim 34 is not amended and is believed to be allowable without amendment.

CONCLUSION

In view of the amendments submitted herein and the above comments, it is believed that all grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Accordingly, the Applicant respectfully requests early and favorable action. Should there be any further questions or reservations, the Examiner is urged to telephone the Applicant's undersigned attorney at (770) 984-2300.

Respectfully submitted,

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